

U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO		Complete If Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT			
(Use as many sheets as necessary)			
Sheet	1	of	4
		Attorney Docket Number	05432/100M919-US1

U.S. PATENT DOCUMENTS

CITED DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (# known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
1	US-6,150,376	11-21-2000	Kozikowski et al.		
2	US-5,776,969	07-07-1998	James		
3	US-5,747,494	05-05-1998	Medjad et al.		
4	US-20040029958	02-12-2004	Sanchez et al.		
5	US-6,469,064	10-22-2002	Druzgala		
6	US-4,079,135	03-14-1978	Maisey et al.		

FOREIGN PATENT DOCUMENTS

Examiner Signature	Date Considered	
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"EXAMINER: If initial reference considered, whether or not citation is in conformance with MPEP 600. Draw through citation if not in conformance and note considered. Include copy of this form with next communication to applicant." CITE NO. Those application(s) which are marked with an asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(ii)) because that application was filed after June 30, 2003 and is available in the IFW. "Applicant's name" is the name of the inventor as indicated in the application. "Year" is the year of the patent or the year of the filing date of the application. "Emperor's name" is the name of the Emperor as indicated in the application. "MPEP 91.06" is the section of the MPEP that discusses the use of Japanese patent documents. "WPTO Standard ST-3." For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. "Kind of document" by the appropriate symbols as indicated on the document under WPTO Standard ST-16 if applicable. "Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 4

Complete if Known

Application Number	10/644,579-Conf. #5200
Filing Date	August 20, 2003
First Named Inventor	Connie Sanchez
Art Unit	1617
Examiner Name	Y. S. Chong
Attorney Docket Number	05432/100M919-US1

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	10	Notice of Opposition to EP Patent No. 1 200 081 filed by EGIS GYOGYSZERGYAR NYRT. (June 14, 2007)	
	11	Notice of Opposition to EP Patent No. 1 200 081 filed by GENERICS (UK) LIMITED. (June 19, 2007)	
	12	Notice of Opposition to EP Patent No. 1 200 081 filed by HEXAL PHARMA AG. (June 20, 2007)	
	13	Notice of Opposition to EP Patent No. 1 200 081 filed by Pliva Hrvatska d.d.i. (June 21, 2007)	
	14	Notice of Opposition to EP Patent No. 1 200 081 filed by Richter Gedeon R.T. (June 20, 2007)	
	15	Notice of Opposition to EP Patent No. 1 200 081 filed by TEVA PHARMACEUTICAL INDUSTRIES LTD. (June 20, 2007)	
	16	NZ Examination Report for NZ App. No. 569150 (June 24, 2008)	
	17	E.J. ARIENS "Chirality in Bioactive Agents and its Pitfalls." TIPS, May 1986:200-205.	
	18	P. BAUMANN, "Care of depression in the elderly: comparative pharmacokinetics of SSRIs," International Clinical Psychopharmacology 1998, Vol. 13 (suppl 5) S35-S43.	
	19	R.J. BOERNER, et al. "The Importance of new Antidepressants in the Treatment of Anxiety/Depressive Disorders." Pharmacopsychiat. 32 (1999): 119-126.	
	20	BONDOLFI, "Non-response to citalopram in depressive patients: pharmacokinetic and clinical consequences of a fluvoxamine augmentation." Psychopharmacology (1998) 128:421-425.	
	21	O. BRAWN-MINTZER, "Psychiatric Comorbidity in Patients with Generalized Anxiety Disorder." Am J Psychiatry 150:8. August 1993, pp 1216 - 1218.	
	22	K. M. CONNOR, "Generalized Anxiety Disorder: Neurobiological and Pharmacotherapeutic Perspectives." Biol Psychiatry 1998; 44:1286-1294.	
	23	CUTLER, "A Double-Blind, Placebo-Controlled Study Comparing the Efficacy and Safety of Ipsapirone Versus Lorazepam in Patients With Generalized Anxiety Disorder: A Prospective Multicenter Trial." Journal of Clinical Psychopharmacology, Vo. 13, No. 6, (1993), pp. 429-437.	
	24	Larry CULPEPPER, M.D., "Escitalopram: A New SSRI for the Treatment of Depression in Primary Care." Primary Care Companion J. Clin Psychiatry 2002;4(6) pp. 209 - 214.	
	25	N. P. EMMANUEL, "Sertraline in Generalized Anxiety Disorder, A Case Series," Psychopharmacology Bulletin, p. 518	
	26	FachInformation, Cipralex® (Escitalopram). (10 mg/20 mg) (Product Description)	
	27	FachInformation, Cipramil® (Citalopram) (20 mg/40 mg) (Product Description)	
	28	FDA's Policy Statement for the Development of New Stereoisomeric Drugs, FDA website, < http://www.fda.gov/cder/guidance/stereo.htm >, printed September 5, 2007	
	29	"Forest Aerobid Market Share is Stable at 10%-10.5%, Firm Reports. (September 28, 1998) Vol. 60, No. 39, p. 19.	

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	30	Shinji HASHIMOTO, Effects of conditioned fear stress on serotonin neurotransmission and freezing behavior in rats, European Journal of Pharmacology 378 (1999) 23-30.	
	31	Shinji HASHIMOTO, Effects of the Co-administration of 5-HT1a Receptor Antagonists with an SSRI in Conditioned Fear Stress-Induced Freezing Behavior, Pharmacology Biochemistry and Behavior, Vol. 58, No. 2, pp. 471-475, 1997.	
	32	Shinji HASHIMOTO, Serotonin reuptake inhibitors reduce conditioned fear stress-induced freezing behavior in rats, Psychopharmacology (1996) 123: pp. 182-186.	
	33	S. HOGG, The antidepressant effects of citalopram are mediated by the S-(+) and not the R(-) enantiomer, European Neuropsychopharmacology, Vol. 9, Supplement 5, 1999, p. S213.	
	34	A.J. HUTT, Drug Chirality and its Clinical Significance," Drugs 1996: 52, Suppl. 5, pp. 1-12.	
	35	Takeshi INOUYE, Serotonergic Activation Reduces Defensive Freezing in the Conditioned Fear Paradigm, Pharmacology Biochemistry and Behavior, Vol. 53, No. 4, pp. 825-831, 1996.	
	36	M. KOSEL, Analysis of the enantiomers of citalopram and its demethylated metabolites using chiral liquid chromatography, Journal of Chromatography B, 719 (1998) pp. 234-238.	
	37	Y.W. Francis LAM, Pharm. D. Stereoselectivity: An Issue of Significant Importance in Clinical Pharmacology, Pharmacotherapy, Vol. 8, No. 3, 1988, pp 147-157.	
	38	G. LAUX, Psychotherapeutic Treatment of Anxiety Disorders, Therapeutische Umschau, Vol. 54, No. 10, 1997, pp. 595-599.	
	39	LEPOLA et al., Citalopram in Anxiety Disorder of Childhood and Adolescence, Eur. Child. Adol. Psych., 1994 3(4):277-279.	
	40	LEPOLA et al., The effect of citalopram in panic disorder and agoraphobia, Nord. J. Psych., 1994, 48:13-17.	
	41	J.P. LHUILLIER, Maprotiline Drops: Pilot Study in Anxiety Adaptive Disorders, Psychiatry Today Accomplishments and Promises, International Congress Series, Elsevier Science Publishers B.V., 1989.	
	42	Lundbeck Annual Report 1999 (C. G. GOTTFRIES, "Citalopram benefits society," p. 26)	
	43	Lundbeck Annual Report 1998 (Development Projects, p. 68)	
	44	R. B. LYDIARD, Recent Developments in the Psychopharmacology of Anxiety Disorders, Journal of Consulting and Clinical Psychology 1996 Vol. 64, No. 4, pp 660-668.	
	45	W. MAIER, The Epidemiology of comorbidity between depression, anxiety disorders and somatic diseases, International Clinical Psychopharmacological, May 1999: 14 Suppl 2: S1-6.	
	46	Merck Manual of Diagnostics, Home Edition, 1997, pp. 438-447	
	47	S. NOBLE, Citalopram: A Review of its Pharmacology, Clinical Efficacy, and Tolerability in the Treatment of Depression, CNS Drugs 1997 Nov: 8 (5): 410-431	
	48	G. PARKER, Early onset depression: the relevance of anxiety, Soc Psychiatry Psychiatr Epidemiol (1997) 32: 30-37.	
	49	Psychopharmaka Rote Liste 1998, Cipramil® (Citalopram HBr) p. 127.	

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